

REMARKS

In reply to the above Office Action, claim 8 has been amended for clarity and to include the subject matter of claim 13 and claim 13 has been cancelled. Claim 14 has also been amended to be consistent with amended claim 8. Support for the starting material being an oxide powder containing yttrium can be found on page 6, lines 11-12 and in claim 14. In addition, claim 15 has been amended to claim “a kit” comprising the catheter and a microsphere. It is believed this should avoid the rejection of claim 15 under 35 U.S.C. §112, second paragraph, and its withdrawal as a ground of rejection of the claim is therefore requested.

In the Office Action, the Examiner continued to reject claims 1-2, 4-5, 7-8, and 13-14 under 35 U.S.C. §103(a) for being obvious over Gray. Further, claims 1-5, 8, and 15 were rejected under 35 U.S.C. §103(a) for being obvious over Gray in view of Day. In addition, claims 1-8 and 10-15 were rejected under 35 U.S.C. §103(a) for being obvious over Gray in view of Day and further in view of Huang.

All of independent claims 1, 8, and 15 recite, amongst other features, that the claimed microsphere “is in the shape of a sphere.” The Examiner notes at page 3, last line to page 4, line 1 of the Office Action, that the primary reference to Gray “fails to specifically state that his microspheres are in the shape of a sphere.” Specifically Gray teaches that they are “hollow or cup-shaped” microspheres. See column 1, lines 12-13 of Gray.

The Examiner believes, however, that the shape of the microspheres is viewed to be a design choice and absence of a showing of unexpected results, would have been an obvious modification of Gray’s microspheres. This belief is further supported by Day which discloses microspheres in spherical form. This is the underlying basis of all of the

noted rejections; namely, that it would have been obvious to make the microspheres of Gray in a spherical shape.

On the contrary, it is believed the Examiner's rejection of the claims for being obvious over Gray alone or in view of Day is not proper and should be withdrawn for the following reasons.

With respect to product claims 1-7 and 15, the claimed radioactive microsphere is easily stabilized in a blood capillary near an affected region by the elastic force of the capillary (see drawing (1) on the attached sheet) because it is in the shape of a sphere. Therefore, the claimed radioactive microsphere is capable of embolizing in the capillary to block any nutritional support toward the affected region while irradiating the region with radiation.

On the other hand, Gray's microspheres may be turned by the blood flow and end up moving somewhere to open the capillary (see drawings (2) - (3) on the attached sheet) because they are irregular in shape and more specifically, cup-shaped. Thus they are not capable of embolizing.

Thus it cannot be said that modifying the shape of the microspheres of Gray is a mere obvious design choice because they do not operate in the same way.

In addition, as previously pointed out, in column 3, lines 8-22 of Gray, the patentee specifically teaches against using solid glass microspheres. Note in lines 15-16 where it states that "these glass microspheres (i.e., solid glass microspheres) have several disadvantages."

Moreover, as also previously pointed out, these "microspheres" that Gray maintains are not suitable for use in his invention are, in fact, the microspheres of Day,

because WO 86/03124 cited in column 3, line 13 of Gray as a disclosure of solid glass microspheres is a counterpart of Day.

How then can it be said to be obvious to modify Gray's hollow or cup-shaped microspheres to be in the shape of a sphere when Gray specifically teaches that it should not be so shaped? As noted in M.P.E.P. §2143.01:

If [the] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)

or

If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)

This is exactly what the Examiner is doing when he argues that it would have been obvious to modify Gray's cup-shaped microsphere to make them spherical microspheres either as a matter of design choice or in view of Day, because in doing so he is making them unsatisfactory for their intended purpose and changing the principle of their operation.

Accordingly, it is submitted that the microspheres of claims 1-5, 7, and 15 cannot be considered obvious over Gray alone in view of Day.

With respect to process claims 8, 10-12, and 14, to demonstrate the difference between the process of Gray and the claimed method, which was explained in the Reply of August 11, 2003, enclosed is a declaration of Mr. Inoue, one of the inventors, comparing the claimed process for making radioactive microspheres as set forth in

claim 8 with the process of Gray's as set forth in Example 3. It is clear from the photographs on page 3 of the declaration that Gray's microspheres are far from being uniformly spherical. This is because the process of Gray cannot produce spherical microspheres since the process requires feeding a powdered based material with a binder into a DC plasma torch.

Contrary to this, in the claimed method a microsphere with a high sphericity is obtained because the raw inorganic materials containing substantially no organic substances are completely melted, with a high frequency induction thermal plasma.

Accordingly, it is submitted that the method of claim 8 and claims 11 and 14 dependent therefrom cannot be considered obvious over Gray alone or in view of Day.

The discussion of Huang in the Office Action is appreciated. While Huang may show that it is known to coat a microsphere with a film of silica, it does not supply what is missing in either of Gray or Day as discussed above, so it is believed that claims 6, 10, and 12 are also not obvious over Gray in view of Day and Huang.

As far as the undersigned is aware, the Examiner has not included the Huang reference in any Form PTO-892 nor have applicants cited it in any Information Disclosure Statement. Please make it of record so that it can be printed on any patent granted on this application as a prior art reference considered by the Examiner.

It is believed claims 1-8, 10-12, 14, and 15 are in condition for allowance.

Please grant any extensions of time required to enter this response and charge
any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

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By:



Arthur S. Garrett
Reg. No. 20,338

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